DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-03-16

December 16, 2002

Ken R. Steber, President
Gulf Medical Services
5937 Berryhill Road
Milton, Florida 32570

Dear Mr. Steber:

Inspection of your medical gas filling operation located at the above address on November 14, 2002, by FDA investigator Courtney A. Hunt, revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). The investigator documented significant deviations from the Current Good Manufacturing Practice (CGMP) Regulations for drugs [Title 21, Code of Federal Regulation, Parts 210 and 211 (21 CFR 210 and 211)] in conjunction with the testing and release for distribution of compressed medical Oxygen USP, causing the products to be adulterated within the meaning of Section 501(a)(2)(B) of the Act.

The inspection revealed there is no assurance that your medical oxygen products meet applicable standards of identity, strength, quality, and purity in that you have failed to test each component lot of bulk oxygen to determine conformance with appropriate specifications prior to use, or in lieu of testing, receive a valid certificate of analysis from your supplier and conduct an identity test [21 CFR 211.165(a) and 21 CFR 211.194]. Refilled cylinders of compressed medical Oxygen USP are not being tested for purity and identity prior to release for distribution [21 CFR 211.165(a)]. A [redacted] oxygen analyzer on hand at your facility is not being used and has not been calibrated as specified by the manufacturer [21 CFR 211.160(b)(4)].

Written procedures are not established for production and process controls designed to assure that your medical oxygen products have the identity, strength, quality and purity they are represented to possess [21 CFR 211.100(a)]. For example, no written procedures are established for receipt and acceptance of incoming bulk compressed oxygen, prefill, fill and post fill cylinder inspections, calibration and maintenance of equipment, purity and identity testing of filled cylinders, completion and review of batch production records, labeling, quarantine procedures, and training of personnel. No quality control unit has been established as required [21 CFR 211.22(a)].

Batch production and control records are incomplete and fail to document that each significant step in the manufacturing operation was accomplished, such as all required prefill, fill, and post fill cylinder inspections and tests [21 CFR 211.188(b)]. No documentation is available to show that batch production records are reviewed and approved by a supervisor prior to release, and there is no assurance that personnel have been adequately trained [21 CFR 211.25(a)].

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all medical gas products you repack and distribute comply with the Act and the CGMP regulations. Other Federal agencies are advised of Warning Letters issued and they may take this information into account when considering the award of government contracts.

These are serious violations of the law and you should initiate prompt corrective action. Failure to correct these violations may result in FDA taking regulatory action without further notice. Such action includes seizure of your medical oxygen products and/or obtaining a court ordered injunction against your firm to prevent further distribution of your medical oxygen products.

We request that you notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct these violations, including any documentation showing that corrections have been achieved. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 555 Winderly Place, Suite 200, Maitland, Florida, 32751, telephone (407) 475-4731.

Sincerely,

Emma R. Singleton
Director, Florida District